UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,136	08/18/2006	Anthony John Ujhazy	3869/049 US	1415

22440 7590 02/25/2008

GOTTLIEB RACKMAN & REISMAN PC
270 MADISON AVENUE
8TH FLOOR
NEW YORK, NY 10016-0601

EXAMINER	
BEHRINGER, LUTHER G	

ART UNIT	PAPER NUMBER
4148	

MAIL DATE	DELIVERY MODE
02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,136	UJHAZY ET AL.	
	Examiner	Art Unit	
	LUTHER G. BEHRINGER	4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☒ Claim(s) *31 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the feedback element of the sleep apneic method must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: On page 3, line 1 there phrase "Fig. 1 shows method" appears to be missing an article. On page 4, line 7 the phrase "simulation of afferent nerves" appears incorrect. On page 5, lines 18 and 19, the phrase "emitted at a 20 Hz" appears to have an extra article. On page 6, line 1, the phrase "The changes the transthoracic" appears to be incorrect.

Appropriate correction is required.

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 32 (The method of claim 7 whereby stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration) has been renumbered 33.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claim 31** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim(s) 1, 2, 4, 5, 14, 16 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by **Park et al. (US 6,904,320)**.

Regarding **claim 1,** Park et al. discloses a method of treating sleep disordered breathing comprising the step of electrical stimulation of nerves to increase muscle tone of upper airway muscles (Col. 3, Lines 1 – 4).

Regarding **claim 2,** Park et al. discloses whereby the afferent nerves are stimulated. Merriam-Webster online dictionary defines afferent as "conveying impulses towards the central nervous system."

Regarding **claim 4,** Park et al. discloses whereby the site of electrical stimulation is in the vicinity of the hypoglossal motor nucleus or excitatory afferent nerve pathways leading to this structure (Col. 3, Lines 9 – 14).

Regarding **claim 5,** Park et al discloses whereby the electrical stimulation comprises trains of electrical pulses (Col. 3, Lines 56 – 57).

Regarding **claim 14,** Park et al discloses whereby stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration (Col. 7, Lines 41 – 44).

Regarding **claim 16,** Park et al discloses a method of detecting respiratory disorders comprising the step of measuring a transthoracic impedance changes via implanted electrodes (Col. 7, Lines 29 – 32).

Regarding **claim 30,** Park et al discloses a method of distinguishing open and closed airway apneic events are distinguished by a combination of implanted electrodes and acoustic transducers (Col. 8, Lines 30 – 33).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim(s) 3, 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320)** in view of **Kallok (US 5,158,080)**.

Regarding **claim 3,** Park et al fails to disclose whereby the site of electrical stimulation is within or adjacent to the genioglossus muscle.

However, Kallok teaches whereby the site of electrical stimulation is within or adjacent to the genioglossus muscle (Col. 3, Lines 38 – 41).

12. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Kallok to provide multiple stimulation locations to improve the efficiency of the sleep apneic therapy method.

Regarding **claim 6,** Park et al fails to disclose whereby the train length is approximately 10-30 pulses.

However, Kallok teaches whereby the train length is around 50 pulses (Col. 3, Lines 19 – 20).

13. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of having multiple stimulation pulse strategies to achieve an open airway that could prevent an apneic event. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to try the 10 – 30

pulses as taught by Kallok, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Regarding **claim 13,** Park et al. fails to disclose whereby stimulation is repeated in accordance with the detected state of the airway.

However, Kallok teaches whereby stimulation is repeated in accordance with the detected state of the airway (Abstract).

14. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Kallok to provide a more efficient therapy method for sleep apnea.

15. Claim(s) 7, 10 – 12 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320)** in view of **Bowers (US 5,207,230)**.

Regarding **claim 7,** Park et al fails to disclose a method of treating sleep disordered breathing comprising the step of mechanical stimulation of nerves to increase muscle tone of upper airway muscles.

However, Bowers teaches a method of treating sleep disordered breathing comprising the step of mechanical stimulation of nerves to increase muscle tone of upper airway muscles (Col. 3, Lines 20 – 23).

16. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Bowers to provide an alternative mechanical stimulation of nerves that more efficiently delivers apneic therapy.

Regarding **claim 10,** Park et al fails to disclose whereby the mechanical stimulation is periodic.

However, Bowers teaches whereby the mechanical stimulation is periodic (Col. 10, Lines 25 – 30).

17. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Bowers to provide periodic mechanical stimulation to more efficiently treat sleep apnea.

Regarding **claim 11,** Park et al. fails to disclose whereby the period is in the order of several seconds of vibration.

However, Bowers teaches whereby the period is in the order of several seconds of vibration (Col. 10, Lines 25 – 30).

18. It would have been obvious to a person having ordinary skill in the art at the time of the invention to apply the technique of extending the period of mechanical vibration by several seconds as taught by Bowers to improve the sleep apnea method as disclosed by Park et al.

Regarding **claim 12,** Park et al. fails to disclose whereby the mechanical vibration occurs at frequencies in the range of 10-50 Hz.

However, Bowers teaches a low mechanical frequency (i.e., 7 – 8 Hz) (Col. 10, Lines 26 – 27).

19. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of having a range of mechanical stimulation frequencies to achieve an open airway that could prevent an apneic event. Thus, it would have been

obvious to a person having ordinary skill in the art at the time of the invention to try the 10 – 50 Hz frequency as taught by Bowers, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Regarding **claim 32,** Park et al. discloses whereby stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration (Col. 7, Lines 41 – 44).

20. Claim(s) 8, 9, 15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320)** in view of **Bowers (US 5,207,230)** and further in view of **Kallok (US 5,158,080)**.

Regarding **claim 8 and 9,** Park et al. in view of Bowers discloses whereby mechanical stimulation is performed by a piezo electric mechanical element (Col. 3, Lines 20 – 23), but fails to disclose it being implanted at a site in the vicinity of the upper airway.

However, Kallok teaches [an] element implanted at a site in the vicinity of the upper airway or adjacent to the base of the genioglossus muscle (Col. 3, Lines 34 – 41).

21. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. in view of Bowers with the teachings of Kallok to provide additional implant locations to improve the efficiency of the sleep apnea therapy device.

Regarding **claim 15,** Park et al. in view of Bowers discloses [an] apparatus for treating respiratory disorders comprising a piezo-electric mechanical element (Bowers Col. 3, Lines 20 – 23), and a controller, adapted to elicit vibration of the element via an

electrical signal (Park et al. Col. 22, Lines 37 – 38), but fails to disclose it being adapted for implant within or adjacent the base of genioglossus muscle.

However, Kallok teaches [an] apparatus adapted for implant within or adjacent the base of genioglossus muscle (Col. 3, Lines 38 – 41).

22. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. in view of Bowers with the teachings of Kallok to provide additional implant locations to improve the efficiency of the sleep apnea therapy device.

Regarding **claim 31,** Park et al. in view of Bowers fails to disclose whereby stimulation is repeated in accordance with the detected state of the airway.

However, Kallok teaches whereby stimulation is repeated in accordance with the detected state of the airway (Abstract).

23. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. in view of Bowers with the teachings of Kallok to provide a more efficient therapy method for sleep apnea.

24. Claim(s) 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320)** in view of **Belalcazar et al. (US 2004/0102712)**.

Regarding **claim 17,** Park et al. fails to disclose a first electrode is placed in the left sub-pectoral region.

However, Belalcazar et al. teaches a first electrode is placed in the left sub-pectoral region (Paragraph [0047]).

25. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Belalcazar et al. to provide additional implant locations that would increase the efficiency of the sleep apnea treating device.

Regarding **claim 18,** Park et al. fails to disclose a second electrode is placed in the right sub-pectoral region.

However, Belalcazar et al. teaches a second electrode is placed in the right sub-pectoral region.

26. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Belalcazar et al. to provide additional implant locations that would increase the efficiency of the sleep apnea treating device.

27. Claim(s) 19, 20 and 24 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320)** in view of **Kim et al. (US 2005/0004610)**.

Regarding **claim 19,** Park et al. fails to disclose whereby the transthoracic impedance is measured by emitting high frequency electrical pulses.

However, Kim et al. teaches whereby the transthoracic impedance is measured by emitting high frequency electrical pulses (Paragraph [0028]).

28. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Kim et al. to provide a reliable means to measure the transthoracic impedance to determine apneic events.

Regarding **claim 20,** Park et al. fails to disclose whereby the transthoracic impedance is measured by emitting high frequency electrical pulses.

However, Kim et al. teaches whereby the frequency of the pulses is high compared to typical respiration or heart rate (Paragraph [0028]).

29. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Kim et al. to provide a reliable means to measure the transthoracic impedance to determine apneic events.

Regarding **claim 24,** Park et al. discloses whereby an impedance signal is compared to a baseline reference (Col. 8, Lines 6 – 10).

Regarding **claim 25,** Park et al. discloses whereby the baseline reference is continuously updated (Col. 7, Lines 65 – 67).

Regarding **claim 26,** Park et al. discloses whereby the signal having rhythmic variations at a rate of between approximately 6 and 25 per minute is taken as being indicative of normal respiration (Col. 7, Lines 9 – 11).

Examiner's Note: One skilled in the art would be aware that normal adult respiration is about 12 times per minute (Hill).

Regarding **claim 27,** Park et al. discloses whereby the signal having a marked reduction in amplitude compared to the reference is taken as being indicative of an obstructive apnea (Col. 7, Lines 11 – 14).

Regarding **claim 28,** Park et al. discloses whereby the signal having a first derivative of near zero is taken as being indicative of central apnea (Col. 1, Lines 54 – 64).

Regarding **claim 29,** Park et al. discloses whereby the signal having a crescendo- decrescendo pattern with a period of approximately 40 to 120 seconds is taken as being indicative of Cheyne-Stokes Respiration (Col. 8, Lines 23 - 26).

Examiner's Note: One skilled in the art would be aware that Cheyne-Stokes Respiration cycles generally last between 30 and 60 seconds (Tompsett).

30. Claim(s) 21 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320)** in view of **Kim et al. (US 2005/0004610)** and further in view of **Hartley et al. (US 6,076,015)**.

Regarding **claim 21,** Park et al. in view of Kim et al. fails to disclose whereby the frequency of the pulses is approximately 20 Hz.

However, Hartley et al. teaches whereby the frequency of the pulses is approximately 20 Hz (Col. 7, Lines 28 – 33).

31. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Kim et al. to provide a reliable means to measure the transthoracic impedance to determine apneic events.

Regarding **claim 22,** Park et al. in view of Kim et al. fails to disclose whereby the pulses are of approximately 1 mA amplitude.

However, Hartley et al. teaches whereby the pulses are of approximately 1 mA amplitude (Col. 7, Lines 37 – 38).

32. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Kim et al. to provide a reliable means to measure the transthoracic impedance to determine apneic events.

Regarding **claim 23,** Park et al. in view of Kim et al. fails to disclose whereby the pulses are of approximately 15 microsecond duration.

However, Hartley et al. teaches whereby the pulses are of approximately 15 microsecond duration (Col. 7, Lines 16 – 22).

33. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park et al. with the teachings of Kim et al. to provide a reliable means to measure the transthoracic impedance to determine apneic events.

Conclusion

34. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Takishima et al. (US 5,178,156), Ottenhoff et al. (US 6,251,126), Freeberg (US 2004/0102712), Richmond et al. (US 6,240,316)**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is

(571)270-3868. The examiner can normally be reached on Mon - Thurs 8:00 - 5:30; 2nd Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Luther Behringer
January 7, 2008

/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4148